

18031

Data Munged
ReportRECOMBINANT DNA ADVISORY COMMITTEE (RAC)
DATA MANAGEMENT REPORT - DECEMBER 1994

IRB/IRB #	PI/ Institution	Approval Dates RAC/ NIN/ FDA/	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression In Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
8810-001 ^a (1969)	Rosenberg/ NIN	RAC/10-3-88 NIN/3-2-89 FDA/	M/TIL (C)	(1) 5-22-89 (2) 8-15-90 ^d	LML6/Neo ^R PA317 (Retrovirus)	GTI	Unlimited	10 (6M/2F)	M-Yes	NA	No	No	9 PD	Open ^d
9007-002 ^{a,b} (3424/ T cells) (4447/ PBSC) (5056/ CB/PC)	St. Jude/ NIN Childrens Hosp. LA	RAC/7-31-90 RAC/2-10-92 ^b NIN/9-6-90 NIN/4-22-92 ^b FDA/9-14-90/ T cells FDA/10-8-92/ PBSC 5-3-93/ CB/PC	T/100/SCID-ADA	(1) 9-14-90/ T cells (2) 1-31-91/ T cells ^d (1) 5-13-93/PBSC ^d (1) 5-15-93/CB/PC (2) 6-6-93/CB/PC	LASH-ADA/Neo ^R GINASVAD/Neo ^R PA317 (Retrovirus)	GTI	10 (M/F)	6 (2F/1 cell) (1F/PBSC) (3M/CB/PC)	T-YesG/YesP (T cells) T-YesG/NoP (PBSC) T-YesG/YesP (CB/PC)	Yes (T cells) No (PBSC) Yes (CB/PC)	No	No	0	Open ^d (d rare disease/no eligible subjects identi- fied)
9007-003 ^a (3654)	Rosenberg/ NIN	RAC/7-31-90 NIN/9-6-90 FDA/	T/C	(1) 1-29-91 (2) 10-12-93 ^d	TNF-Neo ^R /pL125H PA317 (Retrovirus)	GTI/Chiron	50 (M/F)	12 (6M/6F)	T-YesG/YesP	Yes	No	Yes 1 transient elevation of liver function	9 PD	Open ^d
9102-004 ^a	Brenner, et.al./ St. Jude	RAC/2-4-91 NIN/7-12-91 FDA/	M/BM (AML)	(1) 9-9-91 (2) 1-15-93	LML6/Neo ^R GIN6/Neo ^R ,a PA317 (Retrovirus)	GTI	12 (M/F)	12	M-Yes (Published)	NA	No	No	3 EBV-LPD/ pericard- itis/ relapse (2 autops.)	Closed 1-15-93 (Maximum # patients entered on study)
9105-005 ^a	Brenner, et.al./ St. Jude	RAC/3-31-91 NIN/7-12-91 FDA/	M/BM (NB)	(1) 1-27-92 (2) 6-1-92	LML6/Neo ^R ,a GIN6/Neo ^R ,a PA317 (Retrovirus)	GTI	10 (M/F)	6	M-Yes (Published) transmission marrow containing tumorigenic cells	NA	No	No	2 disease relapse	Closed 6-1-92

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9105-006 ^a	Brenner, et.al./ St. Jude	RAC/5-31-91 IRB/7-12-91 FDA/	M/BM (HB)	(1) 1-16-92 (2) 4-9-93	LNL6/Neo ^R G1Ha/Neo ^R ,a PA317 (Retrovirus)	GTI	10 (N/F)	3	N-Yes (Published) *Remission marrow contains tumorigenic cells	NA	No	No	2 disease relapse (1 autop.)	Closed 4-9-93
9105-007 ^a (4115)	Deisseroth/ MD Anderson	RAC/5-31-91 IRB/7-12-91 FDA/1-27-92	M/BM (CML)	(1) 7-31-92 (2) 6-1-93	LNL6/Neo ^R PA317 (Retrovirus)	GTI	10 (N/F, 16-60yr) (5 transpl.)	3 evaluable	N-Yes (Published) *Remission marrow contains tumorigenic cells	NA	1/9 insufficient marking	ND - 2/3 failed to engraft	3 disease relapse	Closed 6-1-93
9105-008	Ledley, et.al./ Baylor	RAC/5-30-91 IRB/7-12-91	M/M (Acute Hepatic Failure)	NA	LNL6/Neo ^R PA317 (Retrovirus)	GTI	6 (N/F)	0	NA	NA	NA	NA	NA	Closed (study will not be initiated)
9105-009 ^a (4176)	Lotze/ U. Pittsburgh	RAC/5-30-91 IRB/1-17-92 FDA/11-8-91	M/TIL (C/Melanoma)	(1) 3-3-92 (2) 9-21-93	LNL6/Neo ^R PA317 (Retrovirus)	GTI	20 (N/F)	4 (2F/2M)	N-Yes	NA	No	No	2 PD	Open
9110-010 ^a (4204)	Rosenberg/ MIM	RAC/10-7-91 IRB/10-15-91 FDA/	T/M/C	(1) 10-8-91 (2) 6-3-94	TRNNeo ^R /pL1123H PA317 (Retrovirus)	GTI/ Chiron	5 (N/F)	4 (1M/3F)	V-NA		No	No	3 PD	Open
9110-011 (1969)	Rosenberg/ MIM	RAC/10-7-91 IRB/10-15-91 FDA/	T/M/C	(1) 3-12-92 (2) 3-18-92 ^d	G1HaCY12 PA317 (Retrovirus)	GTI	5 (N/F)	2 (1M/1F)	V-NA		No	No	2 PD	Open ^d
9110-012 ^a (4393)	Wilson/ U. PA	RAC/10-8-91 IRB/11-16-91 FDA/3-25-92	T/CO/FR	(1) 6-5-92 (2) 3-11-94	CMV-BA-(h)DLR pal-crlp (Retrovirus)	U. PA	5 (N/F)	5	T - YesG/YesP	Yes (Published)	Yes (No xlog gene expression variable)	No	0	Closed 3-11-94 (Maximum # patients entered on study)

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9202-013 ^a (4367) U. MI	Nabel/ U. MI	RAC/2-10-92 NIN/4-17-92 FDA/	T/C	(1) 6-3-92 (2) 11-19-92	pHLA-B2/B-2 (VCL-1005) (Liposome/DNA)	Vical	12 (M/F)	5	T-YesG/YesP	Yes (Published)	No	No	5 (PD)	Closed 11-19-92
9202-014 (4217) Cornetta/ IN U.	Cornetta/ IN U.	RAC/2-11-92 NIN/4-17-92 FDA/11-91	M/BN (AML, ALL)	(1) 4-23-92 (2) 8-17-93	GT1 G1Hs/Neo ^R PA317 (Retrovirus)	GT1	20 (M/F, 18-65 yr) 10 AML 10 ALL	5 (1M/4F) (4 AML/1 ALL)	M-Yes	NA	No sustained marking/ no marked leukemic cells	No	2 1-sepsis 1-relapse	Open
9202-015 Economou/ UCLA	Economou/ UCLA	RAC/2-11-92 NIN/4-17-92 FDA/	M/BB/TIL (C/Melanoma, Renal Cell)	(1) 2-19-93 (2) 6-94	LMG/Neo ^R G1Hs/Neo ^R PA317 (Retrovirus)	GT1	40 (M/F) 20 Melanoma 20 Renal Cell	9 (8M/1F)	M-Yes Primarily renal cell (melanoma minimal)	NA	No	No	5 PD	Closed 8-94
9202-016 ^a (4168) Freeman/ Tulane U./ U. Rochester	Freeman/ Tulane U./ U. Rochester	RAC/2-10-92 NIN/2-5-93 FDA/	T/N/C (Ovarian)	(1) 8-93 (2) 11-7-93	HSV-TK PA317 (Retrovirus)	U. Rochester	20 (F) Divided between Tulane U. and U. Rochester	3 (F)	NE	No	No	Yes Fever, nausea, PD vomiting, abdominal pain	1	Open
9202-017 ^b (4337) Greenberg, et.al./ FRCRC	Greenberg, et.al./ FRCRC	RAC/2-11-92 RAC/9-9-93 NIN/4-17-92 NIN/10-7-93 ^b FDA/	M/CIL (HIV+)	(1) 2-26-93 (2) 8-19-94	MyTK PA317 (Retrovirus)	TGC	30 15 NHL HIV+/ 15 HIV+	7 (M)	M-Yes Transient only		No	No	1 GMD/CMV pneumonia (1 autop.)	Open
9206-018 ^a Grenier, et.al./ St. Jude	Grenier, et.al./ St. Jude	RAC/6-1-92 NIN/8-14-92 FDA/	T/N/C (NB)	(1) 12-9-92 (2) 7-7-94	G1HsCv12 PA317 (Retrovirus)	GT1	12 (M/F)	4 (2M/2F)	M-NA	Yes 71 antitumor response, 3/4 CD16/AC response, 1 eosino- philia	No	No	3 PD (2 autop.)	Open

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9206-019 ^a (4734)	Oldfield/ NIN	RAC/6-1-92 NIN/8-14-92 FDA/	T/C (Brain Tumors)	(1) 12-7-92 (2)	GLS/Ms PA317 (Retrovirus)	GTI	20 (M/F)	15	T-YesG/YesP		Yes Low transduction efficiency	Yes Hemorrhage/tox mortality in 2 patients	11	Additional patients will be enrolled until current data is analyzed
9206-020 ^a (4694)	Deisseroth/ MD Anderson	RAC/6-2-92 NIN/8-14-92 FDA/1-5-93	M/BN/PB (OIL)	(1) 12-17-93 (2) 1-4-94	LRLG/Neo ^R GIRa/Neo ^R PA317 (Retrovirus)	GTI	10 (M/F, 16-60yr)	2 evaluable (4 entered)	M-P	NA	Yes Insufficient marking	No disease relapse	1	Open
9206-021 ^a (4590)	Ganabacher, et. al./ MSKCC	RAC/6-2-92 NIN/8-14-92 FDA/10-92	T/M/C (Melanoma)	(1) 2-17-93 (2) 10-19-94	HAPAD/IL2 GP-SMZ/AM12 (Retrovirus)	MSKCC	12 (M/F)	10 (10M/2F)	V-NA	Yes Stable disease in 1 patient	No	Yes Grade 2 induration/ erythema/ grade 1 pruritus/pain/ fatigue	8 PD (0 autops.)	Closed 10-19-94
9206-022 ^a (4637)	Ganabacher, et. al./ MSKCC	RAC/6-2-92 NIN/8-14-92 FDA/10-92	T/M/C (Renal Cell)	(1) 3-17-93 (2) 10-12-94	HAPAD/IL2 GP-SMZ/AM12 (Retrovirus)	MSKCC	12 (M/F)	11 (8M/3F)	V-NA	Yes Stable disease in 5 patients	No	Yes Grade 1 induration/ erythema/ pruritus/ nausea/fever/ fatigue	7 PD (0 autops.)	Open
9206-023 ^a (4697)	Durbin/ NIN, U. MA	RAC/6-2-92 NIN/8-14-92 FDA/12-92	M/BN/PB (Multiple Myeloma)	(1) 10-28-92 (2) 10-15-94	LRLG/Neo ^R GIRa/Neo ^R PA317 (Retrovirus)	GTI	12 (M/F) Divided between NIN and U. MA	9 (7M/2F)	M-Yes • >18 months 2/6 in granulocytes and lymphocytes	NA	Yes Low transduction efficiency (<1%)	No	0	Open

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9206-024 ^a (4497)	Dunbar/ MIN	RAC/6-2-92 MIN/8-16-92 FDA/12-92	M/BN/PB (Breast)	(1) 11-20-92 (2) 10-6-94	LNL6/Neo ^R GIRa/Neo ^R PA317 (Retrovirus)	GTI	12 (F)	6 (F)	M-Yes ~12 months 1/4 in granulocytes and lymphocytes	NA	Yes Low transduction efficiency (~1%)..	No	3 (2 PD) (1 vena- occlusive liver disease)	Open
9206-025 ^a (4497)	Dunbar/ MIN, U. MA	RAC/6-2-92 MIN/8-16-92 FDA/Pending	M/BN/PB (OIL)	NA	LNL6/Neo ^R GIRa/Neo ^R PA317 (Retrovirus)	GTI	12 (M/F) Divided Between MIN and U. MA.	0	NA	NA	NA	NA	NA	Pending FDA approval
9206-026 ^a (4703)	Valker/ MIN	RAC/9-16-92 MIN/9-3-93 FDA/3-25-94	M/PB (MIV/ Identical Twin)	(1) 6-13-94 (2) 10-21-94	LNL6/Neo ^R or GIRa/Neo ^R PA317 (Retrovirus)	GTI	12 (M/F, >18yr) MIV-identical twin	6 (M)	M-Yes	NA	No	No	0	Open
9209-027 ^a (5173)	Schuening/ FHCRC	RAC/9-16-92 MIN/2-5-93 FDA/12-10-93	M/PB (C/Solid Tumors)	(1) 4-10-94	LNL6/Neo ^R PA317 (Retrovirus)	TCC	20 (M/F)	1	No	NA	Pending -- report to follow	No	1 RSV D17 post transplant	Open
9209-028 ^a	Schuening/ FHCRC	RAC/9-16-92 MIN/2-5-93	M/PBSC (C/Lymphoid Malignancies)	NA	LNL6/Neo ^R PA317 (Retrovirus)	TCC	20 (M/F)	0	NA	NA	NA	NA	NA	Closed
9209-029	Schuening/ FHCRC	RAC/9-16-92 MIN/2-5-93	M/BN/PB (Identical Twin)	NA	LNL6/Neo ^R PA317 (Retrovirus)	TCC	20 (M/F)	0	NA	NA	NA	NA	NA	Merged with 9209-027
														Closed
														Study will not be initiated

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9209-030 ^a (5781)	Deisseroth/ MD Anderson	RAC/9-14-92 HIN/12-2-93 FDA/Pending	M/BM/PB (C/CLL,MHL)	NA	LNL6/Neo ^R G1Na/Neo ^R PA317 (Retrovirus)	GTI	10 (N/F)	0	NA	NA	NA	NA	NA	Pending FDA approval
9403-031/ 9209-031 (Pending)	Roth/ MD Anderson	RAC/9-13-93 RAC/3-4-94 HIN/Pending FDA/Pending	T/C (NSCLC)	NA	LNAS-K-228, LND38 GP-gagM12 (Retrovirus)	MA	14 (N/F)	0	NA	NA	NA	NA	NA	Pending NIH and FDA approval
9209-032	Brenner/ St. Jude	RAC/9-15-92 HIN/2-5-93 FDA/	M/BM (NB)	NA	LNL6/Neo ^R G1Na/Neo ^R PA317 (Retrovirus)	GTI	12 (N/F)	0	NA	NA	NA	NA	NA	Open ^b (^d unable to obtain purging antibodies and vectors in combination)
9209-033 (4029)	Lotze, et.al./ U. Pittsburgh	RAC/9-15-92 HIN/2-5-93 FDA/9-8-93 FDA/1-13-94	T/N/C	(1) 9-9-93 (2) 10-17-94	G1IL6Sw PA317 (Retrovirus)	GTI	20 (N/F)	16 (5 melanoma) (1 renal cell) (2 colon) (5 adeno) (1 clear cell) (2 infiltrat- ing duct)	N-NA T-P	No	Yes	Fever, chills, PO diarrhea, skin irritation	8	Open

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9212-034 ^a	Crytal/ Cornell, Rockefeller U., NIN	RAC/12-3-92 NIN/4-16-93 FDA/4-16-93	T/OD/CF	(1) 4-17-93 (2) 9-26-94	AdCFTR 293 (Adenovirus)	Cornell NIN	24 (M/F, >15 yr) 10 Lung 16 Nasal Divided between NIN, Cornell, and Rockefeller U.	9 (6M/3F)	I-Test/Resp (Published) *Vector-mediated CFTR mRNA and CFTR protein in the respiratory epithelium	Yes (Published)	No	Yes (Published) 1 patient -- mild to moderate fatigue, fever, hypoxemia, pulmonary infiltrate, lung function abnormalities (all symptoms transient)	0	Open
9212-035 ^a (5613)	Wilson/ U. PA, U. MI	RAC/12-3-92 NIN/8-26-93 FDA/7-12-93	T/OD/CF	(1) 9-3-93 (2) 4-25-94	AD-CF-C22A- MS-110CFTR 293 (Adenovirus)	U. PA	44 (M/F) 22/U. MI 22/U. PA	8 (27/6M)			No	No	0	Open
9212-036 ^a (5048)	Welsh, et.al./ NIN	RAC/12-4-92 NIN/4-16-93 FDA/7-13-93	T/OD/CF	(1) 7-26-93 (2) 11-8-93	Ad2/CFTR-1 293 (Adenovirus)	Genzyme	9 (M/F)	4 (2M/2F)	I-Test/Resp (Published) (4/4 patients)	Yes (Published)	No	No	0	Open
9303-037 ^a (5512)	Culver, et.al./ IA Methodist, U. IA, U. WA, UCSF	RAC/3-1-93 NIN/4-16-93 FDA/5-18-94	T/C (Gliblastone Multiforme)	(1) 7-13-93 (2) 10-12-94	GITR15W6 PA317 (Retrovirus)	GTI	60 (M/F, >18 yr) 15 at each site	6 (3M/3F)	NA	No	No	Yes Meningeal inflammation/ pancytopenia/ seizure/severe headache	0	Open
9303-038 ^a	Neelap/ St. Jude	RAC/3-2-93 NIN/4-16-93 FDA/9-93	M/EBV-CTL (C/LexAemia, Malignant Disorders)	(1) 11-16-93 (2) 8-23-94	LML6/Neo ^R GHa/Neo ^R PA317 (Retrovirus)	GTI	35 (M/F)	10 (7M/3F)	M-Test (in press) • Persistence >7 months	NA	No	Yes Mild exacerbation of GVHD	3 1 disease relapse (ALL)/ 1 disease relapse (AML)/ 1 ARD due to septicemia	Open

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9303-039 (5009)	Brenner, et.al./ St. Jude	RAC/3-2-93 NIN/4-16-93 FDA/	M/BH (AML)	(1) 10-12-93 (2) 8-18-94	LML/Neo ^R GIM/Neo ^R PA317 (Retrovirus)	GTI	35 (N/F)	7 (4M/3F)	NA	No	No	1 Candida sepsis DIS (autop. confirmed)	Open
9303-040 (5229)	Simpson/ Johns Hopkins	RAC/3-1-93 NIN/12-2-93 FDA/8-19-93	T/V/C (Renal Cell)	(1) 1-24-94 (2) 10-13-94	MFG-hu-ON-CSF pal-crisp (Retrovirus)	Somatix Therapy	26 (N/F)	11 (3F/8M)	V-NA	No	Yes Grade 1,2 cutaneous reaction at dose level 2 (acral limited to this dose)	3	Open
9303-041 ^a (5291)	Wilmott, et.al./ Children's Hosp., OH	RAC/3-2-93 NIN/4-16-93 FDA/4-6-94	T/100/CF	(1) 9-21-94	AVICF2 293 (Adenovirus)	GTI	15 (N/F)	1 (M)	T-P	No	No	0	Open
9303-042 ^a (5208)	Boucher, et.al./ U. NC	RAC/3-2-93 NIN/10-7-93 FDA/	T/100/CF	(1) 1-11-94	Ad.CB-CFTR 293 (Adenovirus)	U. PA	12 (N/F, >18 yr)	12 (5M/7F)	T-TestG (minimal/none in 2 patients)	Difficult to No Code response	No	0	Closed 10-94 (Maximum # patients entered on study)
9306-043 ^a (5142)	Siegler/ Duke U.	RAC/6-7-93 NIN/9-3-93 FDA/6-12-93	T/V/C (Melanoma)	(1) 8-10-93 (2) 10-11-94	PMUJ-IFN VCRU7 (Retrovirus)	Viagene	20 (N/F)	9 (4M/5F)	V-NA	No	No	3 PD	Open
9306-044 ^a (5561)	Deisseroth, et.al./ MD Anderson	RAC/6-7-93 NIN/12-2-93 FDA/9-2-94	T/C (Ovarian)	NA	MDR-1/LW PA317 (Retrovirus)	ATCC	10 evaluable (F/18-60 yr) Maximum of 20 entered	0	NA	NA	NA	NA	Open Actively recruiting patients

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9306-045 (S178)	Nobel/ U. MI	RAC/6-7-93 WIN/9-3-93 FDA/	T/C	(1) 2-2-94 (2) 10-18-94	pHLA-B7/β-2 (Liposome/DNA)	Vical	24 (N/F) 12 Intratumor 12 catheter	6 (2M/4F)	T-P	T-P	T-P	No	0	Open
9306-046 (Pending)	Barranger/ U. Pittsburgh	RAC/6-7-93 WIN/9-3-93 FDA/Pending	T/ID/G	NA	R-CC pal-crip (Retrovirus)	U. Pittsburgh	5 (N/F)	0	NA	NA	NA	NA	NA	Pending FDA Approval
9306-047 (Pending)	Karlsson, et.al./ WIN, CHLA	RAC/6-7-93 WIN/9-3-93 FDA/Pending	T/ID/G	NA	GIGc PA317 (Retrovirus)	GTI	10 (N/F) 5 BH 5 PB	0	NA	NA	NA	NA	NA	Pending FDA Approval
9306-048 ^a (S107)	Galpin, et.al./ Shared Med. Res. Foundation	RAC/6-7-93 WIN/9-3-93 FDA/8-3-93	T/MIV	(1) 8-10-93 (2) 9-8-94	(MIV-IT(V)) b17 (Retrovirus/ Direct Injection)	Viagene	Minimum of 5 per group (N/F) 10 ⁶ CFU 10 ⁷ CFU	21 (19M/2F)	T-P	T-P	No	No	0	Closed 9-8-94
9306-049 (S320)	Nobel/ U. MI	RAC/6-7-93 WIN/9-3-93 FDA/3-24-94	T/MIV	(1) 5-31-94 (2) 7-19-94	Rev M10, dReM10/pal-crip (Retrovirus) RSV-tar/RevM10, RSV-tar/Rev M10 (Particle Mediated)	Vical	12 (N/F) 4 groups of 3	3 (M)	T-P	T-P	T-P	No	0	Open
9306-050 (S512)	Raffel, et.al./ CHLA	RAC/6-8-93 WIN/9-3-93 FDA/7-25-94	T/C (Malignant Astrocytoma)	NA	GITSM6 PA317 (Retrovirus)	GTI	15 (N/F) If positive response- additional 15 may be accrued	0	NA	NA	NA	NA	NA	In Prepara- tion

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9308-051 (5368)	Resdorffer, et.al./ Columbia U.	RAC/6-8-93 MIN/9-3-93 FDA/	T/C (Breast, Ovarian, and Brain)	NA	PMANDR1A GP+SV40 AM12 (Retrovirus)	MA GTI	20	0	NA	NA	NA	NA	NA	Open
9308-052 (5372)	Ilanv Case Western Reserve	RAC/6-8-93 MIN/12-2-93 FDA/3-24-94	T/N/C (Glioblastoma)	(1) (2)	panti-IgF-I (EBV derived) (Liposome/ Antisense RNA)	Case Western Reserve	12 (M/F)	0	NA	NA	NA	NA	NA	Open
9309-053 (4908)	Cassileth, et.al./ U. Miami	RAC/9-9-93 MIN/12-2-93 FDA/3-3-93	T/N/C SCLC	NA	pBMD-Neo-RIL2 (BPV derived) (Liposome/DNA)	U. Miami	12 (M/F)	0	NA	NA	NA	NA	NA	Open
9309-054 (Pending)	O'Shaughnessy/ MIN	RAC/9-9-93 MIN/10-7-93 FDA/Pending	T/C (Breast)	NA	GTHD PA317 (Retrovirus)	GTI	18 (F)	0	NA	NA	NA	NA	NA	Pending FDA Approval
9309-055 (5312)	Kun, et.al./ St. Jude	RAC/9-9-93 MIN/10-7-93 FDA/5-18-94	T/C (Brain)	NA	GIT5Vna PA317 (Retrovirus)	GTI	6 (M/F)	0	NA	NA	NA	NA	NA	Pending IRB approval
9309-056 (Pending)	Das Gupta, et.al./ U. IL	RAC/9-10-93 MIN/4-19-94 FDA/Pending	T/N/C (Melanoma)	NA	p2IPNeoSV-IL2 GP+SV40AM12 (Retrovirus)	U. IL	12 (M/F)	0	NA	NA	NA	NA	NA	Pending FDA Approval
9309-057	Vong-Staal, et. al./ USD	RAC/9-10-93 MIN/Pending FDA/	T/NIV	NA	pHUT PA317 (Retrovirus)		6 (M/F)	0	NA	NA	NA	NA	NA	Pending NIH approval

NIH/DAID #	PI/ Institution	Approval Dates	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression In Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
9309-058 (Pending)	Economou, et. al./ UCLA	RAC/9-10-93 NIH/12-2-93 FDA/Pending	T/N/C (Melanoma)	NA	GLA332 PA332 (Retrovirus)	Cell	30 (N/F)	0	NA	NA	NA	NA	NA	Pending FDA approval
9312-059 ^a (3448)	Oldfield, et. al./ NIH	RAC/12-2-93 NIH/1-20-94 FDA/	T/C (LC)	(1) 8-8-94 (2) NA	GTTESVW PA317 (Retrovirus)	GTI	20 (N/F)	1 (Intra- vesicular/ 10 VPC)	No	No	No	Yes transient emerging inflammatory response to VPC	0	Pending FDA approval (* closed- ing VPC supply)
9312-060	Sobol, et. al./ SDRCC	RAC/12-2-93 NIH/Pending FDA/	T/N/C (Cancer)	NA	LMC/IL2 PA317 (Retrovirus)		12 (N/F) 9 at maximum tolerated dose	0	NA	NA	NA	NA	NA	Pending NIH approval
9312-061	Schramm/ FHCRC	RAC/12-2-93 NIH/Pending FDA/	T/IGD/G	NA	LGCC PG13 (Retrovirus)	FHCRC	10 (N/F)	0	NA	NA	NA	NA	NA	Pending NIH and FDA approval
9312-062 ^a (5107)	Hindrich/ U. CA at San Diego Treatment Center	RAC/12-2-93 NIH/4-19-94 FDA/11-23-93	T/NIH	(1) 2-23-94 (2) 10-13-94	HIV-1T(V) D17 (Retrovirus/Direct Injection)	Viagen	25 (N/F)	16 (14M/2F)	T-P	T-P	No	No	0	Closed 10-13-94
9312-063 (Pending)	Sznol/ NIH	RAC/12-3-93 NIH/4-19-94 FDA/Pending	T/N/C (Melanoma)	NA	SDCH80-87 (Retrovirus)	NIH	48 (N/F, >15yr) 24 HLA-A1+/ 24 HLA-A2+	0	NA	NA	NA	NA	NA	Pending FDA approval
9312-064 (3411)	Rubio/ Mayo Clinic	RAC/12-3-93 NIH/4-19-94 FDA/2-21-94	T/C (Colorectal)	(1) 5-24-94 (2) 10-5-94	PHLA-B7/B-2 (VCL-1005) (Liposome/DNA)	Vical	15 (N/F, >15yr)	8 (6M/2F)	Yes (T-P)	Yes (T-P)	No	No	1 PD (0 autops.)	Open

NIH/RAC # (FDA IND #)	PI/ Institution	Approval Dates RAC/ NIH/ FDA/	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression In Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
9312-065 (Pending)	Chang/ U. MI	RAC/12-3-93 NIH/8-23-94 FDA/Pending	T/N/C (Melanoma)	NA	GBA4 pal-crfp (Retrovirus)	MA	15 (N/F)	0	NA	NA	NA	NA	NA	Pending FDA approval
9312-066	Sorecher, et.al/ U. AL	RAC/12-3-93 NIH/Pending FDA/	T/ID/CF	NA	pCCT (Liposome/DNA)	Vical	9 (N/F)	0	NA	NA	NA	NA	NA	Pending NIH approval
9312-067 ^a (5342)	Velsh/ MMH, U. VA	RAC/12-3-93 NIH/2-10-94 FDA/2-22-94	T/ID/CF	(1) 4-20-94 (2) 10-3-94	AD2-ORF6/PCR-CFTR, AD2/CFTR-1 293 (Adenovirus)	Genzyme	40 (N/F) 20 NIH 20 U. VA Each site: 10 nasal 10 sinus	4 (M/Nasal)	Yes (T-P)	Yes (T-P) * 2/4 biochemical efficacy	No	No	0	Open
9403-068 ^a	Rosenblatt, et.al./ UCLA, CHLA	RAC/3-3-94 NIH/Pending FDA/	T/N/C (MD)	NA	pMiy-1FN (Retrovirus)	Viagene	10 (N/F)	0	NA	NA	NA	NA	NA	Pending NIH approval
9403-069 (5610)	Velker/ NIH	RAC/3-3-94 NIH/8-23-94 FDA/10-14-94	T/NIH	NA	CRIS(SV40)3- pA317 (Retrovirus)	Cell GeneSys	43 (N/F, >18yr) Doses: 3 single 40 multiple	0	NA	NA	NA	NA	NA	Open
9403-070 (Pending)	Brigham/ Vanderbilt U.	RAC/3-3-93 NIH/Pending FDA/Pending	T/ID/AATD	NA	PCR4-AAT (Liposome/DNA)	Vanderbilt U.	11 (N/F) 6 Nasal 5 Lung	0	NA	NA	NA	NA	NA	Pending NIH and FDA approval

MIN/RAC # (FDA IND #)	PI/ Institution	Approval Dates RAC/ MIN/ FDA/	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression in Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
9403-071 (5411)	Vogelzang/ U. Chicago	RAC/3-4-94 MIN/4-19-94 FDA/2-21-94	T/C (Renal Cell)	(1) 6-1-94 (2) 8-18-94	pHLA-B7/B-2 (VCL-1005) (Liposome/DNA)	Vical	15 evaluable (N/F, >18 yr)	7 (5M/2F)	Yes (T-P)	Yes (T-P)		Yes pain on injection	1 0 (0 autops.)	Open
9403-072 (5411)	Merish, et.al./ AZ Cancer Center	RAC/3-4-94 MIN/4-19-94 FDA/2-21-94	T/C (Melanoma)	(1) 5-13-94 (2) 10-5-94	pHLA-B7/B-2 (VCL-1005) (Liposome/DNA)	Vical	15 evaluable (N/F, >18 yr)	10 (5M/5F)	Yes (T-P)	Yes (T-P)	No	Yes Pain on injection/ 1 patient transient pneumothorax (resolved)	0	Open
9403-073 (Pending)	Curiel/ U. AL	RAC/6-9-94 MIN/Pending FDA/Pending	T/C (Colorectal)	NA	pG137 (Plasmid DNA) Direct Injection	U. AL	15 (N/F)	0	NA	NA	NA	NA	NA	Pending MIN and FDA approval
9406-074 (Pending)	Evans, et.al./ U. Pittsburgh	RAC/6-9-94 MIN/Pending FDA/	T/O/NA	NA	DFG-IRAP-tk pal-crip (Retrovirus)	U. Pittsburgh	6 (N/F)	0	NA	NA	NA	NA	NA	Pending MIN and FDA approval
9406-075 (Pending)	Freedman/ MD Anderson	RAC/6-9-94 MIN/7-12-94 FDA/Pending	M/PB/TIL (C/Ovarian)	NA	Glna/Neo ^R P3317 (Retrovirus)	GTI	9 (F/>16yr)	0	NA	NA	NA	NA	NA	Pending MIN and FDA approval
9406-076 (Pending)	Neelap, et.al./ St. Jude	RAC/6-9-94 MIN/7-12-94 FDA/Pending	M/BHSC (C/Pediatric Malignancies)	NA	LtL6/Neo ^R GTH/Neo ^R P3317 (Retrovirus)	GTI	20 (N/F, >21yr)	0	NA	NA	NA	NA	NA	Pending FDA Approval
9406-077 (Pending)	Deisseroth, et.al./ MD Anderson	RAC/6-9-94 MIN/7-12-94 FDA/	T/C (Breast)	NA	pWDR-1 P3317 (Retrovirus)	MD Anderson (producer cell) ATCC (COP facility)	10 evaluable (F/18-60yr)	0	NA	NA	NA	NA	NA	Pending FDA approval

IRB/IRAC #	PI/Institution	Approval Dates	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression In Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
9406-078 (Pending)	Li, et.al./ MIM	RAC/6-9-94 MIM/7-12-94 FDA/Pending	T/ID/IA	NA	7 PA317 (Retrovirus)	GTI	6 (M/F, >5yr)	0	NA	NA	NA	NA	NA	Pending FDA approval
9406-079 (Pending)	Roth/ MD Anderson	RAC/6-10-94 MIM/Pending FDA/Pending	T/C (NSCLC)	NA	Ad5CMV-p53 293 (Adenovirus)	7	42 (M/F)	0	NA	NA	NA	NA	NA	Pending FDA approval
9406-080 (Pending)	Sobel, et.al./ SDRCC	RAC/6-10-94 MIM/7-12-94 FDA/Pending	T/N/C (Glioblastoma)	NA	GINaCv12.23 PA317 (Retrovirus)	GTI	15 (M/F, >18yr)	0	NA	NA	NA	NA	NA	Pending FDA approval
9408-081 (Pending)	Lotze/ U. Pittsburgh	RAC/6-10-94 MIM/Pending FDA/	T/N/C (Melanoma, T Cell Lymphoma, Breast, Head & Neck)	NA	TIG-hIL-12-Meo pal-crip (Retrovirus)	U. Pittsburgh	18 (M/F)	NA	NA	NA	NA	NA	NA	Pending MIM approval
9408-082 (Pending)	Sinone/ Johns Hopkins	MIM/8-3-94 (Accelerated Review) FDA/Pending	T/N/C (Prostate)	NA	MFG-hu-CK-CSF pal-crip (Retrovirus)	Somax Therapy	26 (M)	0	NA	NA	NA	NA	NA	Pending FDA approval
9409-083 (Pending)	Flotte/ Johns Hopkins	RAC/9-12-94 MIM/Pending FDA/Pending	T/ID/CF	NA	tgAAVCF (AAV)	TGC	16 (M/F)	0	NA	NA	NA	NA	NA	Pending MIM approval
9409-084 (Pending)	Molt, et.al./ Vanderbilt U.	RAC/9-12-94 MIM/Pending FDA/	T/C (Breast)	NA	306santimyc. 306santifos PA317 (Retrovirus/ Antisense RNA)	Vanderbilt U.	10	0	NA	NA	NA	NA	NA	Pending MIM approval

NIH/DAI # (FDA IND #)	PI/ Institution	Approval Dates RAC/ MIN/ FDA/	Category	Dates of Treatment: (1) First Patient (2) Most Recent Patient	Vector Construct Packaging Cell Line (Delivery Vehicle)	Vector Supplier	Maximum Patient Accrual	Patients Entered On Study	In Vivo Evidence Of Gene Transfer And Expression In Target Cells	Evidence Of Biological Activity	Problems Associated With Gene Transfer	Adverse Effects	# Deaths	Protocol Status
9409-085	Crystal/ Cornell, Rockefeller U., MIN	RAC/9-12-94 MIN/Pending FDA/	T/IGD/CF	NA	pAdCMV1/CFTR-1 293 (Adenovirus)	GenVec	26 (M/F)	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-086	Lyerly/ Duke U.	RAC/9-12-94 MIN/Pending FDA/	T/V/C (Breast)	NA	pHP6-IL2 (Liposome/DNA)	ALS	20 (F)	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-087	Whitley/ U. MN	RAC/9-13-94 MIN/Pending FDA/	T/IGD/MS	NA	L2SN/IDS (Retrovirus)	U. MN	2 (M/F)	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-088	Isner, et.al./ St. Elizabeths, Tufts	RAC/9-13-94 MIN/Pending FDA/	T/O/PAO	NA	pHVEGF165 (Plasmid DNA/Direct Injection)	St. Elizabeths/ Tufts	12 (M/F)	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-089	Eck, et.al./ U. PA	RAC/9-13-94 MIN/Pending FDA/	T/C (Malignant Glioma)	NA	pAdRSC16 293 (Adenovirus)	U. PA	18 (M/F) 9 surgically accessible 9 surgically inaccessible	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-090	Albelde, et.al./ U. PA	RAC/9-13-94 MIN/Pending FDA/	T/C (Malignant Mesothelioma)	NA	pAdRSC16 293 (Adenovirus)	U. PA	12 (M/F)	0	NA	NA	NA	NA	NA	Pending MIN approval
9409-091 (5362)	Dorkin, et.al./ New England Med. Ctr., MA General	MIN/10-5-94 (Accelerated Review) FDA/2-22-94	T/IGD/CF	NA	Ad2-CFTR/2 293 (Adenovirus)	Genzyme	24 (M/F) 8 groups of 3	0	NA	NA	NA	NA	NA	In prepara- tion
Total # Patients								329						

* Current data as of October 25, 1994.

LEGEND:

* Minor Modification
 * Major Amendment
 * Expedited Review
 * No Patients Entered On the Study > 1 Year
 M - No Gene Marking Protocol/Marked Cells Not Detected In Vivo (In Vivo Marking Successful)
 M - P Gene Marking Protocol/Data Pending
 M - Yes Gene Marking Protocol/Marked Cells Detected In Vivo
 NA Not Applicable
 ND Not Determined
 NE Not Evaluable
 P Gene Marking Protocol/No Evidence of Successful Marking
 P Pending
 T Gene Therapy
 T - No Gene Therapy Protocol/No Evidence of Gene Transfer In Vivo
 T - P Gene Therapy Protocol/Data Pending
 T - Yes/Yes Gene Therapy Protocol/Evidence of Gene Transfer In Vivo/Evidence of Protein Expression
 T - Yes/No Gene Therapy Protocol/Evidence of Gene Transfer In Vivo/No Evidence of Protein Expression
 V - NA Vaccine Protocol/In Vivo Evidence of Gene Transfer Not Applicable

ACRONYMS:

AATD	Alpha-1 Antitrypsin Deficiency	HHV1	Howard Hughes Medical Institute
AAV	Adeno-Associated Virus	HHV2	Human Immunodeficiency Virus
AIS	Applied Immune Sciences	HS	Hunter Syndrome
ALL	Acute Lymphocytic Leukemia	IGD	Inherited Genetic Disorder
AML	Acute Myelogenous Leukemia	LC	Leptomenigeal Carcinomatosis
ATCC	American Type Culture Collection	MA	Microbiological Associates
BH	Autologous Bone Marrow Cells	MSKCC	Memorial Sloan-Kettering Cancer Center
BH/PB	Autologous Bone Marrow and Peripheral Blood Cells	NB	Neuroblastoma
BHSC	Autologous Bone Marrow Stem Cells	NHL	Politicar Non-Hodgkin's Lymphoma
BPV	Bovine Papilloma Virus	NIN	National Institutes of Health
C	Cancer	NSCLC	Non-Small Cell Lung Cancer
CB	Autologous Cord Blood	O	Other
CF	Cystic Fibrosis	PAD	Peripheral Artery Disease
CFU	Colony Forming Units	PB	Autologous Peripheral Blood Cells
CHLA	Children's Hospital Los Angeles	PBSC	Autologous Peripheral Blood Stem Cells
CLL	Chronic Lymphocytic Leukemia	PC	Placenta Cells
CHL	Chronic Myelogenous Leukemia	PD	Due to Progressive Disease
CTL	Autologous Cytotoxic T Lymphocytes	RA	Rheumatoid Arthritis
EBV	Epstein-Barr Virus	SCID-ADA	Severe Combined Immunodeficiency Due to Adenosine
EBV-CTL	Epstein-Barr Virus Cytotoxic T Cell Lines	SCLC	Small Cell Lung Cancer
FA	Fanconi Anemia	SDRCC	San Diego Regional Cancer Center
FDA	Food and Drug Administration	TCC	Targeted Genetics Corporation
FN	Familial Hypercholesterolemia	TIL	Autologous Tumor Infiltrating Lymphocytes
FNCR	Fred Hutchinson Cancer Research Center	UCLA	University of California, Los Angeles
G-CSF	Granulocyte - Colony Stimulating Factor	USC	University of Southern California
GC	Glucocorticoidase	V	Vaccine (Lethally Irradiated Cells)
GTL	Genetic Therapy, Inc.		
GMD	Graft Versus Host Disease		
H	Autologous Hepatocytes		

CATEGORIES OF HUMAN GENE TRANSFER PROTOCOLS	RAC APPROVED	NIN DIRECTOR APPROVED	DELIVERY VEHICLE (RAC APPROVED)			
			RETROVIRUS	ADENOVIRUS	LIPOSOPE/DNA	ADENO-ASSOCIATED VIRUS
GENE THERAPY (T)	67	52	43	11	9	1
Cancer	42	32	30	3	7	0
Cancer/Non-Vaccine (T/C)	21	15	12	3	2	0
Cancer/Vaccine (T/C/N)	21	17	18	0	5	0
NIV	5	4	5	0	2	0
Inherited Genetic Disorder	18	12	7	8	0	0
Alpha-1-Antitrypsin Deficiency (T/IGD/AATD)	1	0	0	0	2	1 (Liposome/Antisense RNA)
Cystic Fibrosis (T/IGD/CF)	10	7	0	0	1	1 (Particle Mediated)
Familial Hypercholesterolemia (T/IGD/FH)	1	1	0	8	1	0
Fanconi Anemia (T/IGD/FA)	1	1	1	0	0	0
Gaucher Disease (T/IGD/G)	3	2	3	0	0	0
Hunter Syndrome (T/IGD/HS)	1	0	1	0	0	0
SCID-ADA (T/IGD/SCID-ADA)	1	1	1	0	0	0
OTHER	2	0	1	0	0	0
Peripheral Artery Disease (T/O/PAD)	1	0	0	0	0	1
Rheumatoid Arthritis (T/O/RA)	1	0	0	0	0	1 (Plasmid DNA)
GENE MARKING	24	24	24	0	0	0
Bone Marrow Cells (M/BM)	7	7	7	0	0	0
Bone Marrow/Peripheral Blood Cells (M/BM/PB)	5	5	5	0	0	0
Bone Marrow Stem Cells (M/BMSC)	1	1	1	0	0	0
Cytotoxic T Lymphocytes (M/CTL)	2	2	2	0	0	0
Hepatocytes (M/H)	1	1	1	0	0	0
Peripheral Blood Cells (M/PB)	2	2	2	0	0	0
Peripheral Blood Stem Cells (M/PBSC)	2	2	2	0	0	0
Peripheral Blood Cells/Tumor Infiltrating Lymphocytes (PB/TIL)	2	2	2	0	0	0
Tumor Infiltrating Lymphocytes (M/TIL)	2	2	2	0	0	0
TOTAL	91	76	67	11	9	1
						4

Data current as of October 25, 1994.

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November 28, 1994

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